

Original Investigation

Behavioral Treatment for Weight Gain Prevention Among Black Women in Primary Care Practice

A Randomized Clinical Trial

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IMPORTANCE Few weight loss treatments produce clinically meaningful weight loss outcomes among black women, particularly in the primary care setting. New weight management strategies are necessary for this population. Weight gain prevention might be an effective treatment option, with particular benefits for overweight and class 1 obese black women.

OBJECTIVE To compare changes in weight and cardiometabolic risk during a 12-month period among black women randomized to a primary care-based behavioral weight gain prevention intervention, relative to usual care.

DESIGN, SETTING, AND PARTICIPANTS Two-arm randomized clinical trial (the Shape Program). We recruited patients from a 6-site community health center system. We randomized 194 overweight and class 1 obese (body mass index [calculated as weight in kilograms divided by height in meters squared], 25-34.9) premenopausal black women aged 25 to 44 years. Enrollment began on December 7, 2009; 12- and 18-month assessments were completed in February and October 2, 2012.

INTERVENTIONS The medium-intensity intervention included tailored behavior change goals, weekly self-monitoring via interactive voice response, monthly counseling calls, tailored skills training materials, and a gym membership.

MAIN OUTCOMES AND MEASURES Twelve-month change in weight and body mass index and maintenance of change at 18 months.


RESULTS Participants had a mean age of 35.4 years, a mean weight of 81.1 kg, and a mean body mass index of 30.2 at baseline. Most were socioeconomically disadvantaged (79.7% with educational level less than a college degree; 74.3% reporting annual income <\$30 000). The 12-month weight change was larger among intervention participants (mean [SD], -1.0 [0.5] kg), relative to usual care (0.5 [0.5] kg; mean difference, -1.4 kg [95% CI, -2.8 to -0.1 kg]; $P = .04$). At month 12, 62% of intervention participants were at or below their baseline weights compared with 45% of usual-care participants ($P = .03$). By 18 months, intervention participants maintained significantly larger changes in weight (mean difference, -1.7 kg; 95% CI, -3.3 to -0.2 kg).

CONCLUSIONS AND RELEVANCE A medium-intensity primary care-based behavioral intervention demonstrated efficacy for weight gain prevention among socioeconomically disadvantaged black women. A "maintain, don't gain" approach might be a useful alternative treatment for reducing obesity-associated disease risk among some premenopausal black women.

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Promoting clinically meaningful weight loss among black women is a particularly vexing clinical challenge.¹⁻³ Across numerous studies, including vanguard clinical weight loss trials,⁴⁻⁶ black women typically demonstrate smaller and less clinically relevant weight losses than white women and men and black men.⁷ The limited success in promoting clinically meaningful weight loss among this group suggests the need for new weight management approaches.⁸ For black women who are overweight and class 1 obese (body mass index [BMI; calculated as weight in kilograms divided by height in meters squared], 25-34.9), weight gain prevention might be one such strategy.^{9,10}

There are several reasons that weight gain prevention might be an advantageous treatment option for black women in this BMI range. First, several studies have shown that for black women, overweight and class 1 obesity are less strongly associated with all-cause and cardiovascular disease mortality than in white women.¹¹⁻¹⁵ For example, Calle et al¹⁵ found that black women with a BMI between 30 and 35 had an increased mortality risk that ranged up to 17% compared with a 30% to 53% increase for white women. Cardiometabolic risk factors similarly exhibit weaker associations with overweight and class 1 obesity in black women than in white women.¹⁶⁻²¹ For example, Taylor et al¹⁶ reported that type 2 diabetes mellitus, hypertension, and low high-density lipoprotein cholesterol were more strongly associated with BMI among whites than among blacks. Stevens et al²¹ showed that no black women, regardless of BMI, had an incidence of hypertriglyceridemia as high as that of white women with a BMI of 30.

Halting weight gains at the overweight or class 1 obese level might therefore maintain the relative health advantage of black women. However, at approximately 1 kg/y, the mean rate of premenopausal weight gain among black women outpaces the rates among women in other racial or ethnic groups.^{21,22} By age 40 to 59 years, black women have more than twice the prevalence of class 2 obesity than white women and 3 times the prevalence of class 3 (extreme) obesity.²² The combination of rapid premenopausal weight gain^{22,23} and extreme obesity²² contributes to disproportionate chronic disease risk among black women. It is possible that preventing premenopausal weight gains and stabilizing weight in the overweight and class 1 obese range would minimize the accumulation of visceral abdominal fat²³ and reduce the odds of a host of adverse cardiometabolic outcomes.¹¹⁻²¹

Second, black women may be particularly receptive to intervention messages about maintaining weight status. Relative to white women, black women have higher rates of body weight satisfaction, fewer social pressures to lose weight, and sociocultural norms that tolerate heavier body weights.²⁴⁻²⁶ Thus, prevention of weight gain might also be more acceptable than weight loss for black women in the overweight and class 1 obese weight range.

Finally, weight gain prevention can be achieved at lower treatment intensity than is required for weight loss.²⁷ Such strategies are particularly well suited for delivery using electronic health (eHealth) technologies, which have the potential to reach large, high-risk populations at low cost.²⁸ These features make weight gain prevention ideal for primary care

settings, particularly those that serve populations with a disproportionate obesity burden.

We conducted a randomized clinical trial to evaluate the efficacy of a weight gain prevention intervention for overweight and class 1 obese (25-34.9) black female primary care patients in a community health center setting. We hypothesized that, relative to usual care, the intervention would promote weight stability for 12 months that would be maintained 18 months after randomization.

Methods

Study Design

As described elsewhere,²⁹ the Shape Program (hereafter Shape) was a 2-arm parallel-group randomized clinical trial conducted among 194 premenopausal black women with a BMI of 25 to 34.9. Patient enrollment began on December 7, 2009, and 18-month follow-up assessments were completed on October 2, 2012. The Duke University Institutional Review Board and the Piedmont Health Board of Advisors approved all study procedures.

Patients were recruited from 6 community health centers operated by Piedmont Health, a nonprofit, federally qualified community health center system that serves a multi-county service area in central North Carolina. Piedmont's 37 000 registered patients are predominantly racial/ethnic minority (77%) and socioeconomically disadvantaged (98% have a documented household income <200% of the federal poverty level; 59% are uninsured).

Study Participants

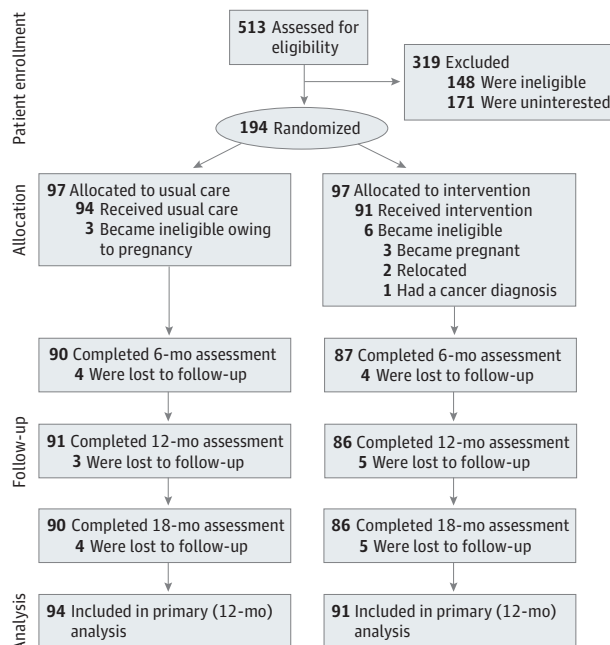
Eligibility criteria included age of 25 to 44 years, BMI of 25 to 34.9, at least 1 visit to a Piedmont Health center in the prior 24 months, North Carolina residency, and self-reported English fluency. Exclusion criteria included pregnancy or postpartum status (≤ 12 months post partum), a history of myocardial infarction or stroke in the prior 2 years, and any history of cognitive, developmental, or psychiatric disorders.

Participant Screening and Recruitment

Piedmont Health staff generated lists of potentially eligible patients at each health center. After assessing BMI eligibility using abstracted anthropometric data, research staff sent potential participants study invitation brochures and guidance for opting out of future contact. No patients opted out of recruitment processes. After 1 week, study staff called patients to screen for eligibility. Eligible patients were asked to attend baseline study visits conducted in private rooms within the health centers or study offices. At these visits, participants provided informed consent and completed study assessments (see the CONSORT [Consolidated Standards for Reporting of Trials] flow diagram in the **Figure**).

After completing baseline assessments, research staff initiated a computer-generated randomization algorithm to allocate participants equally (1:1) across the 2 treatment arms (intervention and usual care); those in the intervention arm were further randomized to 1 of 2 interventionists. The study design precluded blinding patients and interventionists to treatment assignment.

Figure. CONSORT (Consolidated Standards for Reporting of Trials) Flow Diagram



CONSORT flow diagram includes data on patient enrollment, allocation to treatment groups, follow-up, and primary analysis.

Treatment Arms

Usual Care

Study staff made no attempts to influence the medical treatment provided to those in the usual-care arm. Every 6 months, we sent usual-care participants newsletters that covered general wellness topics but did not discuss weight, nutrition, or physical activity.

Weight Gain Prevention Intervention

The Shape intervention is described more fully elsewhere.²⁹ Briefly, it was a theory-based³⁰ and evidence-based³¹⁻³³ treatment designed to create a slight (<200 kcal) daily energy deficit to offset 12-month weight gains. Although a small amount of weight loss is advantageous to prevent future gains, we explicitly informed participants that Shape was not a weight loss trial. We did not expect participants to be motivated to lose weight. Instead, we informed participants that Shape was an approach designed to improve their overall well-being and to maintain their current body shape.

The 12-month intervention used the interactive obesity treatment approach (iOTA)^{31,32} and comprised 5 mutually reinforcing components: (1) tailored behavior change goals; (2) weekly self-monitoring via interactive voice response (IVR) telephone calls; (3) 12 counseling calls delivered monthly by a trained registered dietitian; (4) tailored skills training materials; and (5) a 12-month YMCA membership. Our intervention assigned participants a series of behavior change goals selected from a library of more than 20 goals. If achieved, these goals (eg, no sugar-sweetened beverages, no fast food, replac-

ing energy-dense foods with ≥ 5 fruits or vegetables per day) will create the intended energy deficit.

At baseline and at the 6-month assessment, a computer algorithm assigned each participant 3 behavior change goals based on her need for change, self-efficacy, and readiness. Participants self-monitored their daily adherence to the behavior change goals during IVR calls (2-4 min) that were issued weekly by our computer systems. Brief tailored feedback and short skills training tips were provided after entry of self-monitoring data. Every 2 months, we provided participants with personalized progress reports and replaced 2 of their assigned goals based on their baseline and 6-month survey responses.

Piedmont Health registered dietitians ("Shape coaches"), who were trained in motivational interviewing principles,³⁴ led monthly 20-minute counseling calls. Coaches reviewed patient self-monitoring data, provided skills training and social support, and used goal setting and problem-solving strategies to enhance behavior change self-efficacy. Study staff provided Shape coaches with a 2-day baseline training session, weekly supervision, and refresher trainings every 6 months. Study staff reviewed 5% of coaching calls for protocol adherence.

At baseline and every 2 months thereafter, participants were provided with a set of printed tailored skills training materials (designed for low-literacy audiences).

Measurements

The trial's primary outcomes were change in weight and BMI at 12 months. We also examined maintenance of weight change at 18 months. Participants changed into hospital gowns for physical assessments. Trained staff measured participant heights to the nearest 0.1 cm using a calibrated wall-mounted stadiometer (Seca 214)³⁵; weights were measured to the nearest 0.1 kg with an electronic scale (Seca Model 876).³⁵ Secondary measures included waist circumference, blood pressure, and fasting glucose, triglyceride, and cholesterol levels, assessed using methods described elsewhere.²⁹ All measurements were collected at baseline and at 6-, 12-, and 18-month follow-ups. We provided reimbursements of \$50 each at baseline and at all follow-up study visits. We examined several measures of intervention engagement. These included IVR call completion, defined as the proportion of weekly IVR calls (52 total) resulting in the complete transmission of all self-monitoring data. We also examined the proportion of completed coaching calls (12 total) and use of the provided YMCA membership.

Data Analysis

The primary intent-to-treat analyses were based on the mean difference in weight and BMI between treatment arms at 12 months after adjustment for health center. We used mixed-effects regression models, which included all 185 participants who remained eligible at 12 months, to test a time \times treatment interaction on absolute change in weight and BMI. The mixed-effects regression models used a random intercept and an unstructured covariance matrix. Participants with missing visits were treated as missing at random. Analyses were conducted using Proc MIXED in SAS, version 9.2 (SAS Institute). Similar

modeling was estimated to examine maintenance of weight change 18 months after randomization, as well as change in cardiometabolic risk factors. We examined the proportion of participants who were at or below their baseline weight and tested for differences by software intervention group, controlling for site by using Cochran-Mantel-Haenszel statistic tests for general associations. We also compared blood pressure control (systolic blood pressure <140 mm Hg and diastolic blood pressure <90 mm Hg) between treatment arms across time using generalized estimating equation models with Proc GLIMMIX in SAS software, with a logistic link function, an unstructured covariance matrix, and a random subject effect.

We compared the findings from our intent-to-treat analyses with those from (1) per-protocol models that included only data collected within the window (4 weeks after the 6-, 12-, and 18-month study visits) and (2) models using multiple imputation to replace missing and out-of-window data. Multiple imputation models were based on the assumption of arbitrary missing patterns and used Markov chain Monte Carlo methods, which assume multivariate normality to impute missing values. These analyses followed procedures described in the SAS OnlineDoc (version 8; <http://v8doc.sas.com>) for multiple imputation using 10 generated data sets. Outcomes from these models were in line with the primary intent-to-treat analyses. This trial was designed to have 80% power to detect significant BMI differences of 1.03 between treatment groups 12 months after baseline.

Results

Baseline Characteristics

Participants had a mean (SD) baseline weight of 81.1 (8.8) kg, a mean BMI of 30.2 (2.5) (Table 1), and a mean age of 35.4 (5.5) years. Most participants (79.7%) had an educational level less than a college degree and were currently employed (71%). Many (74.3%) reported an annual income less than \$30 000. Just less than one-third (30.8%) met criteria for the metabolic syndrome, and 21.5% reported depressive symptoms consistent with major depression. There were no baseline differences between treatment arms in weight or sociodemographic characteristics (Table 1).

As shown in the Figure, we enrolled and randomized 194 participants. During the trial, 9 participants became ineligible (3 in the usual-care and 6 in the intervention arm). Of the remaining 185 participants, 177 (95.7%), 177 (95.7%), and 176 (95.1%) completed the 6-, 12-, and 18-month visits, respectively; 169 (91.4%) completed all 4 study visits. Participant attrition did not differ by treatment arm.

Intervention Engagement

Eligible intervention participants completed 81.9% of counseling calls during the 12-month intervention period. Five of 91 participants (5.5%) requested cessation of the counseling calls but continued to use other intervention components. Excluding these participants, the counseling call completion rate averaged 84.3% during the 12-month intervention period. The IVR call completion rate ranged between 65.2% and 89.5% per week, with a mean (SD) of 72% (28%). Of the intervention participants, 64 (70.3%) initiated their free YMCA membership

during the 12-month study period, and 37 (40.7%) of them visited the YMCA more than once.

Weight Gain Prevention

In intent-to-treat analyses (Table 2),³⁶⁻³⁸ the mean (SD) 12-month weight change was significantly larger in the intervention arm (−1.0 [0.5] kg), relative to usual care (0.5 [0.5] kg; mean difference, −1.4 kg; 95% CI, −2.8 to −0.1 kg; $P = .04$). The mean (SD) 12-month change in BMI was similarly larger for intervention participants (−0.3 [0.2]) than for those receiving usual care (0.3 [0.2]; mean difference, −0.6; 95% CI, −1.1 to −0.1; $P = .02$). At 12 months, a significantly larger proportion of intervention participants (62.1%) were at or below their baseline weight compared with those in usual care (45.4%; $P = .03$).

These weight changes were maintained at 18 months. Intervention participants exhibited a mean (SD) 18-month weight loss of −0.9 (0.6) kg, a significant loss compared with usual-care participants who gained a mean of 0.8 (0.6) kg (mean difference, −1.7 kg; 95% CI, −3.3 to −0.2 kg; $P = .03$). The intervention produced a significantly larger mean (SD) 18-month change in BMI (−0.2 [0.2]), relative to usual care (0.4 [0.2]; mean difference, −0.6; 95% CI, −1.2 to −0.1; $P = .03$). By 18 months, more intervention participants (53.2%) than control participants (38.5%) had weights at or below baseline values ($P = .04$).

Change in Cardiometabolic Risk Factors

We observed no differences between treatment arms in change in waist circumference, blood pressure, blood pressure control, glucose, or lipid levels at any time point (Table 3).

Intervention Engagement and Weight Change

The IVR call completion rate was significantly correlated with 12-month weight loss (Spearman $r = -0.2$; $P = .04$); however, 12-month weight loss was not significantly correlated with completion of Shape counseling calls (Spearman $r = -0.2$; $P = .16$).

Adverse Events

Six serious adverse events were reported among participants in the intervention arm, including gynecological surgery in 2 participants and knee replacement, breast abscess, musculoskeletal injury, and cancer diagnosis in 1 participant each; all except the patient with the cancer diagnosis required hospitalization. We could not conclusively determine whether reported events resulted from study participation.

Discussion

Weight gain prevention has potential as a first-line weight management strategy.³⁹⁻⁴¹ By shifting weight gain trajectories, this “maintain, don’t gain” approach may be particularly useful to combat the average 1-kg/y weight gain (and rapid entry into extreme obesity) typically observed among black women. Our findings demonstrate that weight gain can be prevented by using a medium-intensity⁴² eHealth intervention that is easily integrated into the primary care setting. Indeed, we found that the Shape intervention prevented weight gain as intended through 18-month follow-up, and even achieved slight reductions in weight and BMI.

Table 1. Baseline Characteristics of Study Participants

Characteristic	Total (N = 185)	Usual Care (n = 94)	Intervention (n = 91)
Age, mean (SD), y	35.4 (5.5)	35.2 (5.5)	35.6 (5.5)
Weight, mean (SD), kg	81.1 (8.8)	81.0 (8.8)	81.3 (8.8)
Body mass index, mean (SD) ^a	30.2 (2.5)	30.2 (2.4)	30.1 (2.7)
Waist circumference, mean (SD), cm	97.8 (8.2)	97.3 (8.0)	98.2 (8.5)
Blood pressure, mean (SD), mm Hg			
Systolic	123.1 (14.8)	122.9 (14.5)	123.2 (15.3)
Diastolic	80.7 (10.9)	80.4 (11.3)	80.9 (10.7)
Lipids, mean (SD), mg/dL			
Total cholesterol	178.9 (37.5)	181.3 (38.6)	176.4 (36.4)
Triglycerides	102.5 (47.6)	105.0 (54.6)	99.6 (38.1)
HDL cholesterol	53.9 (16.1)	53.9 (16.4)	53.7 (15.8)
LDL cholesterol	107.0 (34.3)	106.8 (34.3)	107.3 (34.6)
Glucose, mean (SD), mg/dL	104.4 (43.2)	105.4 (49.8)	103.4 (35.5)
Educational level, No. (%) ^b			
Less than high school	19 (10.4)	10 (10.8)	9 (10.1)
High school	44 (24.2)	22 (23.7)	22 (24.7)
Vocational or trade school after high school	16 (8.8)	6 (6.5)	10 (11.2)
Some college	66 (36.3)	34 (36.6)	32 (36.0)
College or above	37 (20.3)	21 (22.6)	16 (18.0)
Medical conditions, No. (%)			
Hypertension ^c	67 (36.4)	34 (36.6)	33 (36.3)
Diabetes mellitus ^c	12 (6.5)	5 (5.3)	7 (7.7)
Metabolic syndrome ^d	57 (30.8)	29 (30.9)	28 (30.8)
Depression ^e	38 (21.5)	18 (19.8)	20 (23.3)
Employment status, No. (%) ^b			
Employed	130 (71.4)	66 (70.2)	64 (72.7)
Not employed	52 (28.6)	28 (29.8)	24 (27.3)
Household income/y, No. (%) ^b			
<\$10 000	38 (20.8)	19 (20.7)	19 (20.9)
\$10 000–19 999	52 (28.4)	32 (34.8)	20 (22.0)
\$20 000–29 999	46 (25.1)	23 (25.0)	23 (25.3)
>\$30 000	47 (25.7)	18 (19.6)	29 (31.9)
Poverty, No. (%) ^{b,f}			
Yes	60 (33.0)	33 (35.9)	27 (30.0)
Borderline	53 (29.1)	27 (29.4)	26 (28.9)
No	69 (37.9)	32 (34.8)	37 (41.1)
Tried to lose weight in past 12 mo, No. (%) ^b			
Yes	133 (72.3)	70 (75.3)	63 (69.2)
No	51 (27.7)	23 (24.7)	28 (30.8)

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein.

SI conversion factors: To convert HDL, LDL, and total cholesterol values to millimoles per liter, multiply by 0.0259; to convert triglycerides to millimoles per liter, multiply by 0.0113; to convert glucose values to millimoles per liter, multiply by 0.0555.

^a Calculated as weight in kilograms divided by height in meters squared.

^b Numbers may not sum to 185 because of missing data.

^c Self-reported.

^d The criteria for metabolic syndrome were based on the guidelines developed by the National Cholesterol Education Program's Adult Treatment Panel III report.³⁶ Metabolic syndrome was defined as the presence of ≥3 of the following risk determinants: (1) increased waist circumference (>102 cm [>40 in] for men, >88 cm [>35 in] for women); (2) elevated triglycerides (≥150 mg/dL); (3) low HDL cholesterol (<40 mg/dL in men, <50 mg/dL in women); (4) hypertension (≥130/≥85 mm Hg); and (5) impaired fasting glucose (≥110 mg/dL).

^e Depression score ≥10 on the Patient Health Questionnaire–8 measure.³⁷

^f Poverty thresholds were based on the US Census Bureau 2009 poverty thresholds.³⁸

Several characteristics of Shape should be considered to contextualize our study outcomes. First, nationally, more than half (51.2%) of overweight and obese black women fall within the 25 to 34.9 BMI range.²² This population has elevated risk for future weight gain, extreme obesity, and obesity-associated chronic disease. Our findings may have major clinical and public health significance. Preventing weight gain in this population over time might help maintain the population's lower relative risk of obesity-associated chronic disease and mortality. Second, Shape participants were recruited from a socioeconomically disadvantaged population that has been underrepresented in obesity intervention trials.

Socioeconomic factors are critical drivers of obesity risk behaviors and environments⁴³ and may pose a particular challenge to obesity interventions tested among racial or ethnic minority populations. Third, Shape was conducted in the primary care setting but without primary care providers delivering intervention content. This was an intentional design decision that reflects the challenges facing primary care providers in busy and underresourced community health center settings. We also used inexpensive eHealth technologies to enhance the intervention's reach, accessibility, and scalability. Our findings—particularly the high rates of IVR call engagement and their correlation with greater

Table 2. Change in Weight and Body Mass Index^a

Measure	Mean (SE) Change		Difference, Mean (95% CI)
	Usual Care (n = 94)	Intervention (n = 91)	
Weight, kg			
Month 6	0.1 (0.4)	-1.0 (0.4)	-1.1 (-2.3 to 0.04)
Month 12	0.5 (0.5)	-1.0 (0.5)	-1.4 (-2.8 to -0.1)
Month 18 ^b	0.8 (0.6)	-0.9 (0.6)	-1.7 (-3.3 to -0.2)
Body mass index^c			
Month 6	0.1 (0.2)	-0.3 (0.2)	-0.4 (-0.8 to 0.03)
Month 12	0.3 (0.2)	-0.3 (0.2)	-0.6 (-1.1 to -0.1)
Month 18 ^b	0.4 (0.2)	-0.2 (0.2)	-0.6 (-1.2 to -0.1)

^a Denominators vary because of missing data.

^b The sample included 184 participants at month 18; 1 intervention participant became ineligible owing to pregnancy between 12 and 18 months.

^c Calculated as weight in kilograms divided by height in meters squared.

Table 3. Change in Cardiometabolic Risk Factors^a

Measure	Mean (SE) Change		Difference, Mean (95% CI)
	Usual Care (n = 94)	Intervention (n = 91)	
Systolic blood pressure, mm Hg			
Month 6	-1.2 (1.3)	-1.7 (1.3)	-0.5 (-4.2 to 3.2)
Month 12	-1.6 (1.5)	-1.6 (1.5)	0.01 (-4.1 to 4.2)
Month 18 ^b	0.8 (1.3)	-3.0 (1.4)	-3.8 (-7.6 to 0.2)
Diastolic blood pressure, mm Hg			
Month 6	-1.3 (1.0)	-2.5 (1.0)	-1.1 (-4.0 to 1.7)
Month 12	-1.6 (1.1)	-2.3 (1.2)	-0.7 (-3.9 to 2.5)
Month 18 ^b	-1.0 (1.1)	-1.9 (1.1)	-0.9 (-3.9 to 2.2)
Total cholesterol, mg/dL			
Month 6	0.9 (2.6)	-1.5 (2.6)	-2.4 (-9.7 to 4.8)
Month 12	-2.4 (2.6)	-4.9 (2.7)	-2.5 (-9.8 to 4.9)
Month 18 ^b	-4.5 (2.7)	-4.3 (2.8)	0.1 (-7.6 to 7.8)
Triglycerides, mg/dL			
Month 6	16.2 (6.8)	8.9 (7.2)	-7.4 (-26.8 to 12.1)
Month 12	4.2 (5.9)	6.1 (6.4)	1.8 (-15.3 to 18.9)
Month 18 ^b	1.8 (5.3)	0.2 (5.7)	1.6 (-16.9 to 13.8)
HDL cholesterol, mg/dL			
Month 6	-3.2 (1.1)	-3.2 (1.1)	-0.03 (-3.1 to 3.0)
Month 12	-1.4 (1.2)	-1.6 (1.2)	-0.2 (-3.4 to 3.1)
Month 18 ^b	-1.6 (1.2)	-1.2 (1.2)	0.4 (-3.0 to 3.8)
LDL cholesterol, mg/dL			
Month 6	2.6 (2.9)	-0.8 (3.1)	-3.4 (-11.7 to 4.9)
Month 12	0.1 (2.8)	-5.2 (3.1)	-5.4 (-13.7 to 2.9)
Month 18 ^b	-1.6 (2.9)	-3.3 (3.1)	-1.7 (-10.0 to 6.7)
Waist circumference, cm			
Month 6	-0.8 (0.6)	-1.4 (0.7)	-0.6 (-2.4 to 1.2)
Month 12	0.3 (0.7)	-1.0 (0.7)	-1.3 (-3.1 to 0.5)
Month 18 ^b	-0.2 (0.8)	-1.4 (0.8)	-1.2 (-3.4 to 1.0)
Fasting glucose, mg/dL			
Month 6	5.7 (3.6)	5.8 (3.7)	0.1 (-10.2 to 10.3)
Month 12	-5.1 (2.9)	-1.6 (3.0)	3.5 (-4.7 to 11.7)
Month 18 ^b	-7.4 (3.1)	-3.1 (3.2)	4.3 (-4.5 to 13.1)

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein.

SI conversion factors: To convert HDL, LDL, and total cholesterol values to millimoles per liter, multiply by 0.0259; to convert triglycerides to millimoles per liter, multiply by 0.0113; to convert glucose values to millimoles per liter, multiply by 0.0555.

^a Denominators vary because of missing data.

^b The sample included 184 participants at month 18; 1 intervention participant became ineligible owing to pregnancy between 12 and 18 months.

weight losses—demonstrate that eHealth intervention strategies can be effectively implemented in socioeconomically disadvantaged patient populations that are increasingly adopting such technologies.^{44,45}

Relatively few studies have aimed to prevent weight gain among patients not first exposed to a weight loss intervention,

especially in the US primary care setting. Our findings may be most comparable to those of the Groningen Overweight and Lifestyle study (GOAL), which randomized primary care patients (with hypertension and/or dyslipidemia) to usual care or to a weight gain prevention intervention.⁴¹ The intervention comprised 4 sessions of individual counseling and a telephone-

based feedback session with a nurse practitioner. The GOAL intervention produced significant weight change of -1.4 kg and BMI change of -0.5 at 12 months; like Shape, the GOAL intervention did not produce significant change in blood pressure or lipid levels. However, because GOAL participants were much older and had more comorbid conditions than Shape participants, we suspect that they may have been more motivated to maintain their weight to control their chronic health conditions.

The primary treatment goal of Shape was to create a slight energy deficit sufficient to offset weight gain. Shape was not a weight loss intervention, and participants were fully and frequently informed to this effect. Weight loss, although welcome, was unintended. Interestingly, however, the magnitude of 12- and 18-month weight and BMI change outcomes with Shape exceed those of several behavioral weight loss interventions conducted among black populations,^{31,46-48} particularly those in the primary care setting.³¹ Our findings show that similar levels of weight change can be produced at lower treatment intensity with an eHealth approach and with intervention content focused on weight gain prevention as opposed to weight loss.

The rates of cardiometabolic risk (hypertension, 36.3%; and metabolic syndrome, 30.8%) among Shape participants are concerning; without intervention, this group will probably bear additional chronic disease burden. Weight loss is certainly indicated as a primary treatment approach, particularly given its well-demonstrated ability to produce improvements in cardiometabolic risk.⁴⁹ However, there is little evidence that weight gain prevention will promote reductions in cardiometabolic risk.⁵⁰ Indeed, Shape did not produce changes in cardiometabolic risk factors, although this outcome is perhaps unsurprising given the length of study follow-up and the low magnitude of weight change. Although weight gain prevention might seem controversial given current national guidelines,⁵¹ considering the difficulty in achieving clinically meaningful long-term

weight loss in black women,³ using weight gain prevention to stabilize cardiometabolic parameters might be a reasonably desirable alternative treatment outcome.

Several considerations limit the interpretations drawn from our findings. First, 18 months of follow-up may not have been sufficient to demonstrate the magnitude of our findings; trials of similar interventions with longer follow-up are desirable. Second, our intervention included multiple components and our trial design did not allow us to examine their independent effects. Finally, our trial design did not control for attention; this may have affected outcomes among those randomized to the intervention arm.

Several issues may affect the generalizability of these findings. The Shape intervention was targeted to a large population (51.2% of the overweight and class 1 obese black women). We conducted Shape in a community health center system that has a large, socioeconomically disadvantaged patient population. Although this is a major strength of the trial, our findings may not extend to patient populations in dissimilar settings. Finally, we deemed more than half (53.6%) of those excluded as “uninterested” in participation. More than two-thirds of this group comprised “passive” disinterest. Thus, we have no data on which to base judgments about their reasons for nonparticipation. However, randomized participants did not differ in either age or BMI from those who were uninterested.

In summary, we found that a primary care-based behavioral intervention stabilized weight over 12 and 18 months among overweight and class 1 obese black women. Weight gain prevention has important health benefits for this population and prevention messages have sociocultural salience. Promoting weight loss is a challenge in all populations, but it has been consistently and disproportionately more onerous among black women. It is clear that new treatment approaches, such as weight gain prevention, are necessary to contend with the considerable challenge of obesity in this population.

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